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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/503,656	02/14/2000	William E. Baumzweiger	50065	6960

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EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	PAPER NUMBER
1617	20

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/503,656	Baumzweiger et al
Examiner	**Art Unit**
R.S. Travers J.D., Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 21, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *86-104* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *86-104* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The amendment filed January 21, 2003 has been received and entered into the file.

Applicant's statement regarding those claims presented are incorrect. Applicants aver claims 86-94 are resented, yet claims numbered 86-104 are presented.

Claims 86-104 are presented for examination.

Applicant's election with traverse of group II, claim 5 in Paper No. 16 is acknowledged. The traversal is on the ground(s) that are not set forth . This is not found persuasive because traversal must factually based. Absent an identifiable reason for traversal, objections to the restriction are unconvincing.

The requirement is still deemed proper and is therefore made FINAL.

Claims 86-104 will be examiner to the extent they read on the elected subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines neither those disorders of the central nervous system herein envisioned, nor those therapeutic agents to be employed " that block calcium intake channels on body cells ', "aid in the inhibition of

neural activity in the brain", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", acts "to relieves at least one symptom of psychosis" or is "a growth hormone releasing substance". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these conditions, or compounds required to provide therapy for these conditions without undue experimentation. In the instant case, only a limited number of disorders of the central nervous system are recited; additionally, scant guidance as to those agents useful to "block calcium intake channels on body cells (2)"', "aid in the inhibition of neural activity in the brain(1)", "provides immune system equilibrium(2)", "inhibits body actions that lead to blood clotting(1)", "acts as a chelating agent"(1), acts "to relieves at least one symptom of psychosis(1)" or is "a growth hormone releasing substance (none)" examples are set forth, thereby failing to provide sufficient working examples. Examiner notes Applicants claim all antiviral, antifungal and antibiotic drugs, for treating any disorder of the central nervous system, yet recite in the specification recite 2 antiviral compounds, 2 antifungal compounds and no antibiotic compounds. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all disorders of the central nervous system, save cancer, all therapeutic agents "that block calcium intake channels on body cells ', "aid in the inhibition of neural

activity in the brain", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", acts "to relieves at least one symptom of psychosis" , is "a growth hormone releasing substance", an antiviral compound, an antifungal compound, or an antibiotic, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 86-104 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 100 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for growth hormone, does not reasonably provide enablement for a growth hormone releasing substance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

Claims 86-104 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 86-104 are rendered indefinite by the phrases "a disorder of the central nervous system", drugs "that block calcium intake channels on body cells ', "aid in the

inhibition of neural activity in the brain", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", acts "to relieves at least one symptom of psychosis" , are "a growth hormone releasing substance", an antiviral compound, an antifungal compound, or an antibiotic, and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining diseases which are "a disorder of the central nervous system", or drugs "that block calcium intake channels on body cells ', "aid in the inhibition of neural activity in the brain", "provides immune system equilibrium", "inhibits body actions that lead to blood clotting", "acts as a chelating agent", acts "to relieves at least one symptom of psychosis" , are "a growth hormone releasing substance", an antiviral compound, an antifungal compound, or an antibiotic are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's terms fail to clearly define the subject matter encompassed by the instant claims, thus are properly rejected under 35 USC 112, second paragraph.

connected, to make or use the invention commensurate in scope with these claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 86, 87, 89,90, 91, 92, 93, 94, 95, 97, 98, 99, 101, 102, 103, 104 are rejected under 35 U.S.C. § 102(b) as being anticipated by Baumzweiger (3).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 86, 87, 89,90, 91, 92, 93, 94, 95, 97, 98, 99, 101, 102, 103, 104 are rejected under 35 U.S.C. § 103 as being unpatentable over Baumzweiger (4) and Baumzweiger (3).

Baumzweiger (4) teaches the Gulf War Syndrome (GWS) as a "Brainstem-Limbic" disorder. Baumzweiger (3) teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Taught by Baumzweiger (3), at pages 5-8, as useful concomitantly for treatment

of "Gulf War Syndrome" are various calcium channel blockers, gabatil, as useful for treating "a disorder of the central nervous system", or a useful "aid in the inhibition of neural activity in the brain", celebrex, as an agent that "provides immune system equilibrium", EDTA, as a compound that "inhibits body actions that lead to blood clotting", or "acts as a chelating agent", with klonapin, acting "to relieves at least one symptom of psychosis" ,AZT, as an antiviral compound, zithromax, as an antibiotic, vitamin C, to deal with oxidative stress, and provides direction to the skilled artisan in the diagnosis of this malady and outlines these compounds use for providing treatment. Additionally, Baumzweiger teaches oxidative stress as integral to GWS, renders obvious the use of oxidative compounds to therapy of such conditions (see pages 3-5). These medicament are taught as useful for treating gulf war syndrome, viewed by the skilled artisan as indistinguishable from those conditions herein claimed. Claims 86, 87, 89,90, 91, 92, 93, 94, 95, 97, 98, 99, 101, 102, 103, 104, and the primary reference, differ as to:

1) the concomitant employment of these medicaments,

It is generally considered prima facie obvious to combine two, or more, compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the

concomitant use of two conventional anti-inflammatory agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.

Russell Travers
Primary Examiner
Art Unit 1617